

K203410 ENFit Disposable Enteral SyringeJun 28, 2021
221 days to decisionK203410 · Product code: **PNR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k203410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteral Syringes With Enteral Specific Connectors (PNR)
Date received	Nov 19, 2020
Decision date	Jun 28, 2021
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shantou Wealy Medical Instrument Co.,Ltd
Location	Echo, OR, US
Contact	Yang Songling
510(k) history	6 submissions · 6 cleared · 2012-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Eva Li

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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